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10/581,810	03/12/2007	Luis Miguel Ortega Mora	HERR13.001APC	1935

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/581,810	Applicant(s) ORTEGA MORA ET AL.	
	Examiner Mark Navarro	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5-8, 10-14, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 15-18 and 21 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/5/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants response filed December 5, 2008 has been received and entered. Claim 4 has been cancelled and new claims 21-22 have been added. Consequently, claims 1-3, and 5-22 are pending in the instant application, of which claims 1-3, 5-8, 10-14, and 19-20 have been withdrawn from further consideration as being drawn to a non-elected invention.

Election/Restrictions

Applicants have asserted that a copy of the Foreign Priority Application was received by the USPTO on June 2, 2006 and that an English translation is submitted in the instant response, and that accordingly Spanish Patent Application No. P200302869, filed December 4, 2003 cannot be used in a finding of lack of unity. Applicants assertions are correct concerning Spanish Patent Application No. P200302869, however Applicants will again find a 102(B) rejection below which continues to defeat unity of invention. Accordingly, Applicants request to examine all claims is denied in view of the rejection under 35 USC 102(B) found below.

Claim Objections

1. The objection of claims 15-18 under 37 CFR 1.75(c) as being in improper form is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 101

2. The rejection of claims 9 and 15-16 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

3. The rejection of claims 9 and 15-18 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained.

Applicants are asserting that a species within the claimed genus is disclosed in the specification in Example 2, wherein a recombinant protein was derived from SEQ ID NO: 10 to obtain a denatured polypeptide bound to a poly-histidine tag. Applicants assert that a person skilled in the art would be familiar with procedures such as chemical and/or enzymatic treatment of polypeptide sequences that would give rise to additional species within the claimed genus. Applicants have further included a 1.132 Declaration by Luis Mora demonstrating the conservation of the antigenic characteristics of modified polypeptide is demonstrated with the specific recognition of this antigenic sequence by sera from cattle chronically infected by *Neospora caninum*. Applicants Declaration further shows that two different truncated proteins were recognized by polyclonal serum generated against rNcSAG4 with gpi anchor or without the anchor.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that a species within the claimed genus is disclosed in the specification in Example 2, wherein a recombinant protein was derived from SEQ ID NO: 10 to obtain a denatured polypeptide bound to a poly-histidine tag. However, a single species is simply not commensurate in scope with the breadth of the claims. Claim 9 recites "comprising SEQ ID NO: 10; ***chemically or enzymatically modified sequences of SEQ ID NO: 10 conserving their antigenic characteristics...***" (Emphasis added). For example the starting protein SEQ ID NO: 10 could be treated with any number of enzymes as directly stated in the claim, e.g., trypsin, which would cleave the carboxyl terminus of Lys or Arg. The truncated peptide could then be further treated with other enzymes and/or chemicals to synthesize a larger polypeptide. The amount of divergence is essentially limitless.

Second, Applicants assert that a person skilled in the art would be familiar with procedures such as chemical and/or enzymatic treatment of polypeptide sequences that would give rise to additional species within the claimed genus. However, the claims are not directed to methods of chemical or enzymatic treatment of polypeptides, rather the claim is to a polypeptide, which is the end result of nebulous chemical or enzymatic treatment. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Finally, Applicants have included a 1.132 Declaration by Luis Mora demonstrating the conservation of the antigenic characteristics of modified polypeptide is demonstrated with the specific recognition of this antigenic sequence by sera from cattle chronically infected by *Neospora caninum*, and further shows that two different truncated proteins were recognized by polyclonal serum generated against rNcSAG4 with gpi anchor or without the anchor. However, Applicants Declaration is simply not commensurate in scope (protein truncated by removal of gpi anchor) with the vast array of polypeptides which can be created from SEQ ID NO: 10 by “chemical or enzymatic modification.”

Claims 9 and 15-18 recite chemically or enzymatically modified sequences of SEQ ID NO: 10 conserving their antigenic characteristics.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, “chemically or enzymatically modified sequences of SEQ ID NO: 10 conserving their antigenic characteristics” alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. There is no teaching regarding amino acids can vary from SEQ ID NO: 10, and still

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result in a protein that conserves its antigenic characteristics. Furthermore, there is no disclosed or art-recognized correlation between any structure other than SEQ ID NO: 10 and the activity of conserving antigenic characteristics. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide

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sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.”

Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, the guidelines can be found at the following link on the USPTO Internet in “Patents Guidance.”

<http://www.uspto.gov/web/patents/guides.htm>

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

4. The rejection of claims 15-18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide enablement for vaccine compositions is withdrawn in view of Applicants amendment.

5. The rejection of claims 9 and 15-18 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of “chemically or enzymatically modified sequences derived from sequences homologous to SEQ ID NO: 10” is withdrawn in view of Applicants amendment.

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6. The rejection of claims 9 and 15-18 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "derived from SEQ ID NO: 10" is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The rejection of claims 9 and 15-18 under 35 U.S.C. 102(b) as being anticipated by Krishnan et al is withdrawn in view of Applicants amendment.

The following new ground of rejection is applied to the amended claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 9, 15-18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1033405.

The claims are directed to an isolated polypeptide selected from (a) antigenic protein NcSAG4 of *N. caninum* comprising SEQ ID NO: 10; (b) chemically or enzymatically modified sequences of SEQ ID NO: 10 conserving their antigenic characteristics; (c) NcSAG4 polypeptides of SEQ ID NO: 10 conserving their antigenic characteristics; and (d) a recombinant protein including protein or polypeptide of (a), (b) or (c).

EP 1033405 disclose of *Arabidopsis thaliana* protein fragments and compositions. EP 1033405 specifically disclose of SEQ ID NO: 24,275, which contains the amino acid sequence "G-D-T-Q-V" (amino acids 48-52 of SEQ ID NO: 24,275). This is a 100% match with amino acids 71-75 of the instantly claimed SEQ ID NO: 10. (See attached sequence alignment).

Given that the stretch of five consecutive amino acids disclosed by EP 1033405 is 100% identical with the instantly claimed amino acids 71-75 of SEQ ID NO: 10, it is deemed to anticipate the instantly recited claim language of a chemically or enzymatically modified sequence "conserving their antigenic characteristics." Furthermore, this five consecutive amino acid sequence is also deemed to be an "immunogenic portion" as recited in new claim 21.

Note: The EP 1033405 document exceeds the amount of material that may be electronically transmitted, accordingly, only the sequence alignment printout result is being furnished.

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
February 2, 2009